PATENT COOPERATION TREATY

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REC'D 21 MAR 2006
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 54-000510PC	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/US04/21813	International filing date *(day/month/year)* 07 July 2004 (07.07.2004)	Priority date *(day/month/year)* 07 July 2003 (07.07.2003)
International Patent Classification (IPC) or national classification and IPC IPC: C12N 9/10(2006.01),15/12(2006.01),15/54(2006.01);C12P 21/00(2006.01) USPC: 435/252.3,193,91.4,320.1,13,69.1;536/23.2		
Applicant THE SCRIPPS RESEARCH INSTITUTE		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 60 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☒ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☒ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
22 December 2004 (22.12.2004)	13 February 2006 (13.02.2006)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Achutamurthy Ponnathapura F. Roberts for Telephone No. (571) 272-1600

Form PCT/IPEA/409 (cover sheet)(April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/21813

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4(a))

☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:

pages 1-92 as originally filed/furnished
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☒ the claims:

pages 93-99 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☒ the drawings:

pages 1-6 as originally filed/furnished
pages* NONE received by this Authority on
pages* NONE received by this Authority on

☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages
☐ the claims, Nos
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages
☐ the claims, Nos
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/21813

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has, within the applicable time limit:
   - ☐ restricted the claims.
   - ☐ paid additional fees.
   - ☐ paid additional fees under protest, and, where applicable, the protest fee
   - ☐ paid additional fees under protest but the applicable protest fee was not paid
   - ☐ neither restricted the claims nor paid additional fees

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
   - ☐ complied with.
   - ☒ not complied with for the following reasons:

See Lack of Unity section of the International Search Report Form PCT/ISA/210.

4. Consequently, this report has been established in respect of the following parts of the international application:
   - ☒ all parts
   - ☐ the parts relating to claims Nos.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/21813

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

The international application is not signed by at least one applicant. In additon the title as appearing in box I of the request is not identical with the title heading the description.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/21813

Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:

a. type of material

☒ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☒ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed

☐ filed together with the international application in electronic form

☒ furnished subsequently to this Authority for the purposes of search and/or examination

☐ received by this Authority as an amendment* on _____

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

* *If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/21813

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-49	YES
	Claims NONE	NO
Inventive Step (IS)	Claims 1-49	YES
	Claims NONE	NO
Industrial Applicability (IA)	Claims 1-49	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)

Claims 1-49 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the specific orthogonal glutamyl-tRNA/orthogonal tRNA synthetase pair to be used in producing proeins with unnatural amino acids. Applicants priority document discloses glutamic acid synthetase/OtRNA pair that suppress amber nonsense codons used to incorporate a variety of unnatural amino acids into proteins. In addition although orthogonal glutaminyl-tRNA/tRNA synthetases have been discoled in the prior art, glutamyl-tRNA/tRNA synthetases pairs have not been found disclosed in the prior art. Archeabacterial derived glutamyl not availabe before the priority date of the instant application.

Claims 1-49 meet the criteria set out in PCT Article 33(4), and thus have industial applicability because the subject matter claimed can be made or used in industry.

PATENT COOPERATION TREATY

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NOTE OF INFORMAL COMMUNICATION WITH THE APPLICANT

(PCT Rule 66.6)

International application No.	Applicant's or agent's file reference	Date of informal communication *(day/month/year)*
PCT/US04/21813	54-000510PC	14 February 2006 (14.02.2006)

Applicant
THE SCRIPPS RESEARCH INSTITUTE

Communication

☒ by telephone

☐ personal

Participants

☐ Identity checked ☐ authorization checked ☐ personally known

☒ Applicant: THE SCRIPPS RESEARCH INSTITUTE

☒ Agent: Attorney Jonathan Quine

☒ Examiner(s): Kagnew Gebreyesus

Summary of communication:

Applicants agent agreed to receive the 409 international preliminary examination report.

☐ ~~An extension of time limit is granted (Form PCT/IPEA/427.~~

☒ A copy of this note is being sent to the applicant with Form PCT/IPEA/416 & 409.

Name and mailing address of the IPEA/US	Authorized officer
Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450	Achutamurthy Ponnathapura
Facsimile No. (571) 273-3201	Telephone No. (571) 272-1600

Form PCT/IPEA/428 (July 1992; reprint January 2004)